DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 4, 2014

Molnlycke Health Care, US, LLC
Curtis D. Truesdale, RAC
Director, Regulatory Affairs for the Americas
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092

Re: K141719
Trade/Device Name: Biogel® PI Micro Surgical Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: August 4, 2014
Received: August 5, 2014

Dear Mr. Curtis D. Truesdale,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141719

Device Name

Biogel PI Micro Surgical Glove

Indications for Use *(Describe)*

The Biogel PI Micro Surgical Glove is a disposable device made of Poly-Isoprene material that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared:	August 4, 2014
Applicant:	Mölnlycke Health Care US, LLC 5550 Peachtree Parkway, Suite 500 Norcross, GA 30092 Registration number: 3004763499 Owner/Operator Number: 8030877
Official Correspondent:	Curtis Truesdale Director, Regulatory Affairs of the Americas Tel: 678-250-7928 Fax: 678-245-7746 email: curtis.truesdale@molnlycke.com
Trade/Proprietary Names:	Biogel® PI Micro Surgical Glove
Regulation Name:	Surgeon's Glove
Device Class:	Class I
Regulation Number:	21 CFR 878.4460
Product Code:	KGO
Predicate Device Name(s):	Biogel® PI Surgical Glove (K050184)

Reason for 510(k) Submission:

This 510(k) supports a design modification made to the Biogel® PI Surgical Glove (reference code 408) that was previously cleared through 510(k) K050184. The design modifications consist of a reduction in material thickness from 0.62 $\pm$ 0.06 mm to 0.42 $\pm$ 0.04 mm and the removal of the donning coating. In order to commercially distinguish the modified version from the original glove, the modified glove is branded under the trade name Biogel® PI Micro Surgical Glove, reference code 485, and the original glove remains branded under the trade name Biogel PI Surgical Glove, reference code 408.

Description of Device:

The subject device is a single-use disposable powder-free surgical glove that is supplied sterile and made from synthetic Poly-Isoprene material (not made from natural rubber latex). The gloves are manufactured using hand-specific molds (right and left hand). Each glove contains a beaded cuff to help reduce cuff roll-down during use.

Intended Use/Indication for Use:

The Biogel® PI Micro Surgical Glove is a disposable device made of Poly-Isoprene material that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious materials and other contaminants.

Technological Characteristics:

Biogel® PI Micro Surgical Gloves were produced as a result of modifications made to the existing Biogel® PI Gloves that were previously cleared through 510(k) K050184. The gloves that were produced through these device modifications remain substantially equivalent in terms of technological characteristics, material formulation and intended use. The most notable technological differences between the subject and predicate Biogel® gloves are material thickness and donning coating. These technological characteristics and design modifications implemented for the subject device have been assessed and confirmed that the standard requirements that are appropriate for surgical gloves have been met. The following table is a summary of these technological characteristics in relation to standardized requirements.

Summary of technological characteristics of the device compared to the predicate device		
Feature	Biogel® PI Micro Synthetic Polyisoprene Surgical Glove	Biogel® Polyisoprene Non-latex Sterile Powder-Free Surgeon's Glove *(Trade name reflected in 510k filing)*
	Subject Device (modified version of the predicate)	Predicate Device
510(k) clearance	K141719	K050184
Manufacturer	Mölnlycke	Mölnlycke
Regulation number	21CFR 878.4460	21CFR 878.4460
Regulation name	Surgeon's Glove	Surgeon's Glove
Regulatory class	Class I	Class I
Product code	KGO	KGO
Intended use	Powder-Free Surgeon's Glove	Powder-Free Surgeon's Glove

Indication for use	Biogel® PI Micro Synthetic Polyisoprene Surgical glove is a disposable device made of polyisoprene that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contaminants	Polyisoprene Non-Latex Sterile Powder-Free Surgeon's Glove is a disposable device made of polyisoprene that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contaminants
Material	Synthetic Polyisoprene	Synthetic Polyisoprene
Design	Single use	Single use
	Sterile	Sterile
	Powder-free	Powder-free
	Hand specific	Hand specific
	Beaded cuff sprayed with an antislip polychloroprene band below the bead.	Beaded cuff sprayed with an antislip polychloroprene band below the bead.
Thickness	0.42 ± 0.04 mm	0.62 ± 0.06 mm
Coating	No	Yes
Colour	Natural	Natural
Sterilisation method	Radiation	Radiation
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL
Dimensions & physical properties	Meets ASTM D3577	Meets ASTM D3577
Freedom from holes	AQL meets 21 CFR 800.20 and ASTM D3577 requirements	AQL meets 21 CFR 800.20 and ASTM D3577 requirements
Powder residual	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577	Meets requirements of ≤ 2.0 mg/glove for Powder-free designation per ASTM D3577
Performance Test Data Summary – New Modified Device		
Characteristics	Standard/Test/FDA Guidance	Results Summary
Biocompatibility :		
Primary Skin Irritation	ISO 10993-10	Under the conditions of the study, not an irritant.
ISO Closed Patch Sensitization	ISO 10993-10	Under the conditions of the study, not a sensitizer.
Physical characteristics :		
Dimensions	ASTM D3577	Length: 284 - 310 mm, meet the ASTM minimum requirements of 245 mm for size 5½ and 265 mm for size 6 to 9.

		Width : 71 -116 mm, meet the ASTM requirement of 70 - 114 ± 6 mm.
		Thickness : ≥ 0.30mm, Exceeds the ASTM minimum requirement of 0.10 mm.
Physical Properties	ASTM D3577	Results meet requirements for rubber surgical gloves before and after accelerated ageing.
	Before ageing :	**Average Values Before ageing :**
	Tensile strength : 17 MPa min	Tensile strength : 28 - 29 MPa
	Stress at 500% elongation : 7.0 MPa max. AQL 4.0	Stress at 500% elongation : 1.8 - 1.9 Mpa
	Ultimate elongation : 650 % min	Ultimate elongation : 1100 -1120 %
	After accelerated ageing :	**Average Values After accelerated ageing :**
	Tensile strength : 12 MPa min	Tensile strength : 22- 24 MPa
	Ultimate elongation : 490 % min	Ultimate elongation : 1100 - 1140%
Freedom from holes	21 CFR 800.20 and ASTM D3577 tested according to ASTM D5151	Passed AQL 0.65, exceeds 21 CFR 800.20 and ASTM D3577 requirements of AQL 1.5
Powder residual	ASTM D3577 tested using ASTM standard D6124	Glove meets powder level requirements for "Powder-free" designation per ASTM D3577 testing using ASTM standard D6124. Results generated values below 2 mg of residual powder per glove.
Clinical testing :		
Clinical data is not required		

Conclusion:

The subject devices are substantially equivalent to the Biogel® Surgical Gloves previously 510(k) cleared (K050184) with respect to design, technological characteristics, and intended use and conformance to standard requirements.